

who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(8) NDA.—The term “NDA” means a New Drug Application, as defined under section 505(b) et seq. of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b) et seq.)

SEC. 05. NOTIFICATION OF AGREEMENTS.

(a) IN GENERAL.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(vii)(IV)) and a brand name drug company that enter into an agreement described in paragraph (2), prior to the generic drug that is the subject of the application entering the market, shall each file the agreement as required by subsection (b).

(2) DEFINITION.—An agreement described in this paragraph is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the subject of the generic drug applicant's ANDA;

(B) the manufacture, marketing or sale of the generic drug that is the subject of the generic drug applicant's ANDA; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) FILING.—

(1) AGREEMENT.—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that the generic drug applicant and the brand-name drug company shall not be required to file an agreement that solely concerns—

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any other agreements not described in subsection (a)(2) between the generic drug applicant and the brand name drug company which are contingent upon, provide a contingent condition for, or are otherwise related to an agreement which must be filed under this title.

(3) DESCRIPTION.—In the event that any agreement required to be filed by paragraph (1) or (2) has not been reduced to text, both the generic drug applicant and the brand name drug company shall file written descriptions of the non-textual agreement or agreements that must be filed sufficient to reveal all of the terms of the agreement or agreements.

SEC. 06. FILING DEADLINES.

Any filing required under section 5 shall be filed with the Assistant Attorney General and the Commission not later than 10 business days after the date the agreements are executed.

SEC. 07. DISCLOSURE EXEMPTION.

Any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this title shall be exempt from disclosure under section 552 of title 5, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of Congress or to any

duly authorized committee or subcommittee of the Congress.

SEC. 08. ENFORCEMENT.

(a) CIVIL PENALTY.—Any brand name drug company or generic drug applicant which fails to comply with any provision of this title shall be liable for a civil penalty of not more than \$11,000, for each day during which such entity is in violation of this title. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) COMPLIANCE AND EQUITABLE RELIEF.—If any brand name drug company or generic drug applicant fails to comply with any provision of this title, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General or the Commission.

SEC. 09. RULEMAKING.

The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5 United States Code, consistent with the purposes of this title—

(1) may define the terms used in this title;

(2) may exempt classes of persons or agreements from the requirements of this title; and

(3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this title.

SEC. 10. SAVINGS CLAUSE.

Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this title shall not bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant at any time under any other provision of law, nor shall any filing under this title constitute or create a presumption of any violation of any antitrust or competition laws.

SEC. 11. EFFECTIVE DATE.

This title shall—

(1) take effect 30 days after the date of enactment of this title; and

(2) shall apply to agreements described in section 05 that are entered into 30 days after the date of enactment of this title.

NOTICES OF HEARINGS/MEETINGS

COMMITTEE ON RULES AND ADMINISTRATION

Mr. LOTT. Mr. President, I wish to announce that the Committee on Rules and Administration will meet on Tuesday, June 24, 2003, at 9:30 a.m., in room 301 of the Russell Office Building, to consider the markup of pending legislative and administrative business, including any other items that may be ready for consideration.

For further information concerning this meeting, please contact Susan Wells at 202-224-6352.

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

Mr. COCHRAN. Mr. President, the Committee on Agriculture, Nutrition and Forestry will hold a full committee hearing on Thursday, June 26, 2003, at 9 a.m., in SR-328A, Russell Senate Office Building. The purpose of this hearing is to review H.R. 1904, the Healthy Forests Restoration Act of

2003. Witnesses to be announced at a later date.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON ARMED SERVICES

Mr. THOMAS. Mr. President, I ask unanimous consent that the Committee on Armed Services be authorized to meet during the session of the Senate on Friday, June 20, 2003, at 9:30 a.m., in closed session to receive briefing on Iraqi reconstruction and humanitarian assistance activities.

The PRESIDING OFFICER. Without objection, it is so ordered.

PRIVILEGE OF THE FLOOR

Mr. GRAHAM. Mr. President, I ask unanimous consent that Mr. James Holloway, Derrick Walters, and Mindy Yergin, interns and members of my staff, be granted floor privileges during the consideration of this legislation.

The PRESIDING OFFICER. Without objection, it is so ordered.

MEASURE PLACED ON CALENDAR—H.R. 8

Mr. FRIST. Mr. President, I understand that H.R. 8 is at the desk and is due for a second reading.

The PRESIDING OFFICER. The clerk will read the bill for a second time.

The assistant legislative clerk read as follows:

A bill (H.R. 8) to make the repeal of the estate tax permanent.

Mr. FRIST. I ask unanimous consent that the Senate proceed to the measure and I object to further proceeding.

The PRESIDING OFFICER. Objection is heard. The bill will be placed on the calendar.

AMENDING THE COMMUNICATIONS SATELLITE OF 1962

Mr. FRIST. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of H.R. 2312.

The PRESIDING OFFICER. The clerk will state the bill by title.

The assistant legislative clerk read as follows:

A bill (H.R. 2312) to amend the Communications Satellite of 1962 to provide for an orderly dilution of the ownership interest in Inmarsat by former signatories to the Inmarsat Operations Agreement.

There being no objection, the Senate proceeded to the bill.

Mr. FRIST. Mr. President, I ask unanimous consent that the bill be read the third time and passed, the motion to reconsider be laid upon the table, and that any statements relating to the bill be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (H.R. 2312) was read the third time and passed.